



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,360	01/26/2001	Peng C. Tang	038602/1081	4781

7590

09/24/2003

Beth A. Burrous
FOLEY & LARDNER
Washington Harbour, Suite 500
3000 K Street, N.W.
Washington, DC 20007-5109

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 09/24/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/769,360

Applicant(s)
TANG et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 30, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 12, 15, 17, 20, 21, 23, 25-28, 31, 33, 34, and 37-39 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28 is/are allowed.
- 6) ☒ Claim(s) 1, 11, 12, 15, 17, 20, 21, 23, 25-27, 31, 33, 34, and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1624

DETAILED ACTION

Claims 1, 11, 12, 15, 17, 20, 21, 23, 25-28, 31, 33, 34 and 37-39 are pending in the application.

This action is in response to applicant's amendment filed June 30, 2003. Claims 2, 16, 22, 24 and 32 have been canceled and claims 1, 11, 12, 15, 17, 20, 23, 26-28 and 34 have been amended.

Response to Amendment

Applicant's arguments filed June 30, 2003 have been fully considered with the following effect:

1. With regards to the 35 USC § 112, first paragraph rejection of claims 1, 2, 11, 12, 15-17 and 20-25 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated that "claim 1 has been amended such that it recites specific diseases and conditions originally set forth in claim 22". However, cancer and fibrotic disorders is not a specific disease nor is melanoma, glioma, etc. In the art of clinical oncology, no compound has yet shown clinical efficacy against every type of cancer. Different agents are used for different specific forms of cancer and no single agent is listed as a treatment of every single type of cancer. No compound has shown clinical efficacy against all cancers, thus no *in vivo* or *in vitro* assay could be validated for the identification of such a general agent. Applicants' specification logically must lack such assay data. There is no basis for the treatment of a serine/threonine protein kinase related disease in the specification, nor is there any testing to

Art Unit: 1624

indicate that the compounds of the instant invention are effective in the treatment of a serine/threonine protein kinase related disease.

Claims 1, 11, 12, 15, 17, 20, 21, 23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

2. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejections of claims 17 and 20-25 labeled paragraph 5 of the previous office action which is hereby **withdrawn**.

3. With regards to the 35 USC § 112, first paragraph rejection of claims 17 and 20-25 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated that "claims 22 and 23 recite specific diseases or disorders that are known in the art at this time and the time the application was filed". However, cancer and fibrotic disorders is not a specific disease nor is melanoma, glioma, etc. In the art of clinical oncology, no compound has yet shown clinical efficacy against every type of cancer. Different agents are used for different specific forms of cancer and no single agent is listed as a treatment of every single type of cancer. No compound has shown clinical efficacy against all cancers, thus no *in vivo* or *in vitro* assay could be validated for the identification of such a general agent.

Applicants' specification logically must lack such assay data. There is no basis for the treatment

Art Unit: 1624

of a serine/threonine protein kinase related disease in the specification, nor is there any testing to indicate that the compounds of the instant invention are effective in the treatment of a serine/threonine protein kinase related disease.

Claims 17, 20, 21, 23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

4. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejections of claim 27 labeled paragraph 7 of the previous office action which is hereby **withdrawn**.

5. The applicant's amendments are sufficient to overcome the 35 USC § 112, first paragraph rejections of claims 1, 2, 11, 17, 21-27, 33, 34 and 37-39 labeled paragraph 8 of the previous office action which is hereby **withdrawn**.

6. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled 9a), 9b), 9c), 9d), 9e), 9f), 9g), 9h), 9i), 9j), 9k), 9l), 9m), 9o), 9p), 9q), 9r), 9s) and 9t) of the last office action, which are hereby **withdrawn**.

However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled 9n) in the last

Art Unit: 1624

office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- n) The applicants' stated that the amendment to these claims obviate this rejection. However, claims 15 and 20 were amended such that R_6 - R_9 replaced the variables R_3 - R_6 , respectively around the pyrrole ring. However, the variables R_6 - R_9 are associated with the five membered ring attached to the quinazoline-based compounds of formula I which are bound to the quinazoline-based compound through $(CR_{11}R_{12})_n$ -Z and thus must have at least one atom between the five membered ring and the quinazoline ring.

Claims 15 and 20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

7. With regards to the 35 USC § 102, anticipation rejection of claims 26-28 and 31-33 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated that this rejection has been overcome by the exclusion of compound A-19 from the scope of claims 26-28. However, compound A-19 has not been excluded from claim 31.

Claims 31 and 33 are rejected under 35 U.S.C. 102(e, f and g) as being anticipated by Shenoy et al., U.S. Patent Numbers 6,248,771. For reasons of record.

Art Unit: 1624

8. The applicant's arguments are sufficient to overcome the 35 USC § 103, obviousness rejection of claims 26-28 and 31-33 of the last office action, which is hereby **withdrawn**.

In view of the amendment dated June 30, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 23, 26, 27, 33, 34 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- a) The amendment to the definition of R₁, R₂, R₃, R₄, R₅, R₆, R₇, R₈ and R₉ where R₁, R₂, R₃, R₄, R₅, R₆, R₇, R₈ and R₉ is benzyl is not described in the specification within the genus of formula I and III. (Claims 1 and 23)
- b) The amendment to the definition of R₁, R₂, R₃, R₄, R₅, R₆, R₇, R₈ and R₉ where R₁, R₂, R₃, R₄, R₅, R₆, R₇, R₈ and R₉ is -OX₇, where X₇ is selected from the group consisting of hydrogen, saturated or unsaturated alkyl, and a five-membered or six-

Art Unit: 1624

membered aryl or heteroaryl ring moiety is not described in the specification within the genus of formula I and III. (Claims 1 and 23)

- c) The amendment to the definition of Z' where the ring is optionally substituted with one, two or three alkyl, halogen, trihalomethyl, carboxylate, and ester moieties is not described in the specification within the genus of formula III. (Claims 1 and 23)
- d) The amendment to the definition of R₃, R₄, R₅, R₆, R₇, R₈ and R₉, where the exclusion of the proviso following the definition (a) hydrogen is not described in the specification within the genus of formula I and III. (Claims 26, 27, 33, 34 and 37-39)
- e) The amendment to the definition of R₃, R₄, R₅, R₆, R₇, R₈ and R₉, where the exclusion of the proviso following the definition (b) saturated or unsaturated alkyl is not described in the specification within the genus of formula I and III. (Claims 26, 27, 33, 34 and 37-39)
- f) The amendment to the definition of R₃, R₄, R₅, R₆, R₇, R₈ and R₉, where the exclusion of the proviso following the definition (d) halogen or trihalomethyl is not described in the specification within the genus of formula I and III. (Claims 26, 27, 33, 34 and 37-39)

Applicant is required to cancel the new matter in the reply to this Office action.

Art Unit: 1624

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 11, 17, 20, 21, 23, 25-27, 33, 34 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1, 11, 20, 23, 27 and 33 are vague and indefinite in that it is not known what is meant by the definition of X_7 where X_7 is a five-membered aryl.
- b) Claims 11, 27 and 33 are vague and indefinite in that the definition of R_3 , R_4 , R_5 , R_6 , R_7 , R_8 and R_9 includes $C(X_6)_3$ which is embraced by trihalomethyl and thus results in double inclusion. See Ex parte White 127 USPQ 261.
- c) Claims 17, 21, 26 and 33 are vague and indefinite in that it is not known what is meant by the definition of A_4 and. It is believed that a space is needed.
- d) Claims 17, 21, 26, 33, 34 and 37-39 are vague and indefinite in that it is not known what is meant by the definition of and A_5 . It is believed that a space is needed.
- e) Claim 20 recites the limitation "-OX₇, where X₇ is selected from the group consisting of hydrogen, saturated or unsaturated alkyl, and a five-membered or six-membered aryl or heteroaryl ring moiety" in the definition of R_6 , R_7 , R_8 and R_9 . There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1624

- f) Claims 26, 33, 34 and 37-39 are vague and indefinite in that it is not known what is meant by the definition of X_{13} and X_{14} where X_{13} and X_{14} is a five-membered aryl.
- g) Claims 26, 27 and 33 recite the limitation "pyrrole" in the compound excluded at the end of the claim with respect to formula I. There is insufficient antecedent basis for this limitation in the claim.
- h) Claims 27 and 33 are vague and indefinite in that it is not known what is meant by the definition of R_6 , R_7 , R_8 and R_9 , which is an arylring. It is believed that a space is needed.
- i) Claims 25 and 33 are vague and indefinite in that it is dependent upon a canceled claim.

Allowable Subject Matter

Claim 28 is allowed. None of the prior art of record nor a search in the pertinent art area teaches the compounds as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

Art Unit: 1624

The fax phone number for this Group is (703) 308-4734 for “unofficial” purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink that reads "Brenda Coleman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Brenda Coleman
Primary Examiner AU 1624
September 22, 2003